

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

<b>IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION</b>	<b>MDL No. 2875</b>
<b>THIS DOCUMENT RELATES TO ALL CASES</b>	<b>HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)(KMW)</b>

---

**PLAINTIFFS' *DAUBERT*  
MOTION TO EXCLUDE TESTIMONY OF  
LAUREN J. STIROH, PH.D.**

---

MEYER WILSON, CO., LPA  
900 Camp Street  
Suite 337  
New Orleans, LA 70130

On the Brief:  
Layne C. Hilton

## **TABLE OF CONTENTS**

I.	INTRODUCTION.....	1
II.	APPLICABLE LAW .....	1
III.	ARGUMENT .....	3
	A.    Dr. Stiroh's Opinions Regarding a "Hypothetical But-For World" Must be Excluded.....	3
	1.    Dr. Stiroh's "But-For" World Opinions Are Untethered from the Legal Theory of the Case .....	3
	B.    Dr. Stiroh's Opinions on Alternative Products Must Be Excluded .....	5
	1.    Opinions Related to Alternative Products Stem from the Flawed Counterfactual "But-For" World Dr. Stiroh Constructs .....	5
	2.    Whether TPPs Would Have Purchased Alternative Products Is Not a Viable Defense .....	6
IV.	CONCLUSION.....	7

## TABLE OF AUTHORITIES

### **CASES**

<i>Daubert v. Merrell Dow Pharms., Inc.,</i> 509 U.S. 579 (1993).....	2
<i>Elcock v. Kmart Corp.,</i> 233 F.3d 734 (3d Cir. 2000) .....	2
<i>In re Paoli R.R. Yard Pcb Litig.,</i> 35 F.3d 717 (3d Cir. 1994) .....	2
<i>Meadows v. Anchor Longwall &amp; Rebuild, Inc.,</i> 306 F. App'x 781 (3d Cir. 2009).....	2
<i>Padillas v. Stork-Gamco, Inc.,</i> 186 F.3d 412 (3d Cir. 1999).....	1
<i>Sherwin-Williams Co. v. PPG Indus.,</i> 2020 U.S. Dist. LEXIS 156549 (W.D. Pa. June 18, 2020) .....	2
<i>Steyck v. Bell Helicopter Textron, Inc.,</i> 295 F.3d 408 (3d Cir. 2002) .....	2

## **I. INTRODUCTION**

It is axiomatic that an expert's testimony, at its core, must assist the trier of fact in understanding disputed issues in the case. While Dr. Stiroh's class certification report may have been sufficiently reliable for the purposes of class certification, now, at the merits stage and on the eve of a trial with TPP Plaintiffs, a new inquiry must be conducted on Dr. Stiroh's merits expert report, submitted on June 29, 2023 (attached as Exhibit 1 and reference hereafter "Stiroh Rpt.").

Upon review, it is clear that Dr. Stiroh's opinions regarding a "but-for" world delineating how TPPs *would have acted* absent the Defendants' misconduct are too divorced from the legal record developed in this case since class certification. Rather than be helpful (as *Daubert* requires), the challenged testimony would only serve to confuse. For the reasons more fully articulated below, these opinions regarding the "but-for" world must be excluded.

## **II. APPLICABLE LAW**

The admissibility of expert testimony is determined pursuant to Federal Rule of Evidence 702. The party offering the proposed expert testimony bears the burden of establishing the admissibility of the testimony by a preponderance of the evidence. *Padillas v. Stork-Gamco, Inc.*, 186 F.3d 412, 417-18 (3d Cir. 1999).

Under Rule 702, the opinion of a qualified expert witness is admissible if: (1) it "will help the trier of fact to understand the evidence or to determine a fact in

issue;” (2) it “is based on sufficient facts or data;” (3) it “is the product of reliable principles and methods;” and (4) “the expert has reliably applied the principles and methods to the facts of the case.”

An expert's testimony is helpful if it “will aid the jury in resolving a factual dispute.” *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 F. App'x 781, 790 (3d Cir. 2009). The Third Circuit has emphasized that the expert's analysis must “fit” his or her conclusions to the case at hand. *In re Paoli R.R. Yard Pcb Litig.*, 35 F.3d 717, 745 (3d Cir. 1994). This requirement “goes primarily to relevance” and “requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Daubert v. Merrell Dow Pharmas., Inc.*, 509 U.S. 579, 591 (1993). In other words, expert testimony based on assumptions lacking factual foundation in the record is properly excluded. Importantly, the Third Circuit has held that “[i]t is an abuse of discretion to admit expert testimony which is based on assumptions lacking any factual foundation in the record.” *Steyck v. Bell Helicopter Textron, Inc.*, 295 F.3d 408, 414 (3d Cir. 2002) (citing *Elcock v. Kmart Corp.*, 233 F.3d 734, 756 & n.13 (3d Cir. 2000)).

Even if evidence is relevant, it is excludable “if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury.” *Sherwin-Williams Co. v. PPG Indus.*, No. 2:17-cv-01023-JFC, 2020 U.S. Dist. LEXIS 156549, at \*11 (W.D. Pa. June 18, 2020).

### **III. ARGUMENT**

#### **A. Dr. Stiroh's Opinions Regarding a "Hypothetical But-For World" Must be Excluded**

The underlying and pervasive issue that undermines the entirety of Dr. Stiroh's opinions about TPPs is her complete misconstruction of a "hypothetical but-for-world." Stiroh Rpt. at 12. In her report, Dr. Stiroh opines: "in a hypothetical but-for analysis, by failing to analyze which alternative actions a TPP would have taken had the at-issue VCDs not been available to them, Dr. Conti ignores that TPP Plaintiffs and class members would likely have been in a worse economic position without" the at issue VCDs. *Id.* However, this analysis is so completely removed from the 6-year long record of this case, that it must be excluded from being presented before the jury.

##### **1. Dr. Stiroh's "But-For" World Opinions Are Untethered from the Legal Theory of the Case**

As a threshold issue, Dr. Stiroh's recitation of the "but-for" world modeling in and of itself is unreliable. The "but-for" analysis (of modeling large market factors to determine damage) is a practice routinely (and almost exclusively) conducted in antitrust cases. This is because the legal theories underpinning antitrust law requires the parties to assess how market factors would impact pricing. However, these "market" factors are not at all relevant to the instant case, predicated on duty, warranty and representation.

Even Dr. Stiroh would agree that that a “good damages model is based on a logical and well-specified theory that connects the alleged bad acts to the amount of damage.” Exhibit 2, pg. 8. As the record through summary judgment briefing has made clear, the alleged bad acts are as follows: Defendants warranted they were selling valsartan manufactured in a cGMP compliant way that was safe, effective, free from undisclosed contaminants, and the same as the reference listed drug. The product purchased by TPPs was not. As such, the damages which flowed from that transaction at the point of sale are what matters, and any of the other hypothetical drugs, payments or costs are totally irrelevant to this – a case which seeks damages for the breach of warranty or duty which occurred at the point of sale.

Consequently, if Dr. Stiroh were appropriately modeling the “but-for” world of this litigation, she would have modeled the economic impact of a situation where the Defendants would have complied by their obligations and would have manufactured drugs that did not contain NDMA or NDEA. But Dr. Stiroh did no such thing. Instead, rather than model the economic impact of Defendants appropriately complying with cGMPs and selling drugs that meet such standards (free of NDMA and NDEA), Dr. Stiroh grafts an economic model used in price fixing antitrust cases to model every other market factor totally removed from Defendants’ manufacture and sale of Valsartan. Because Dr. Stiroh’s testimony

about the “but-for” world fails to account for Defendants’ challenged conduct in any way, it fails to meet the primary “fit” requirement of expert testimony. Consequently, any such reference to the “but-for” world must be excluded on this basis alone.

**B. Dr. Stiroh’s Opinions on Alternative Products Must Be Excluded**

**1. Opinions Related to Alternative Products Stem from the Flawed Counterfactual “But-For” World Dr. Stiroh Constructs**

Dr. Stiroh further opines that “TPPs would have paid for alternative medications in a but-for world where Defendants VCDs were not available” and that “the TPPs were likely financially better off as a result of greater supply and competition in the market for VCDs.” Stiroh Rpt. at 12.

This testimony about “alternative medications” stems from the same flawed opinions about what a counterfactual but-for world looked like. In the correct counterfactual world (one that is wedded to the actual challenged conduct and record developed thus far in this case), the Defendants would have manufactured drugs that were safe and effective, contained no NDMA or NDEA, and were the “same” as the reference listed drugs (“RLDs”).

Even if, *arguendo*, Dr. Stiroh was correct that somehow the cost of “alternative drugs” was relevant (which it is not), she does not even attempt to set forth a methodology for calculating the cost of these “alternative” drugs. This is

likely because the exercise would be purely speculative, and not wedded in the actual facts of the record and the challenged conduct of the Defendants. This further demonstrates the unreliability of this expert testimony and the potential confusion it may cause the jury.

## **2. Whether TPPs Would Have Purchased Alternative Products Is Not a Viable Defense**

Dr. Stiroh's "alternative products" theory is not a viable defense in consumer products litigation, so it will not even assist the trier of fact in understanding any disputed legal issues in the case. Taking Dr. Stiroh's opinion regarding "alternative products" to its logical end, there would be no viable consumer goods litigations (be it individual or class), because a defendant would be able to claim that the Plaintiffs would have purchased something else. This is nonsensical. The reason Courts do not even entertain these types of irrelevant arguments is because **damages are losses attributable to a wrong**. What Plaintiffs might have done and how they might have spent their money in a completely counterfactual world has no bearing on the loss that was traceable to the breach of warranty that stemmed from these Defendants' wrongful conduct. Allowing the jury to hear testimony and evidence about a defense that the Defendants cannot cognizably assert would only serve to confuse.

#### **IV. CONCLUSION**

For the foregoing reasons, the Court should exclude Dr. Stiroh's opinions on how a TPP would have acted in the "But-For" World and testimony regarding the TPPs purchase of "alternative products."

Dated: February 12, 2024

Respectfully,

By: /s/ Layne C. Hilton

Layne C. Hilton

MEYER WILSON. CO., LPA

900 Camp Street, Suite 337

New Orleans, LA 70130

614-255-2697

[lhilton@meyerwilson.com](mailto:lhilton@meyerwilson.com)

*On Behalf of MDL PEC and TPP Trial Plaintiffs*

#### **CERTIFICATE OF SERVICE**

I hereby certify that on this 12th day of February, 2024, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing exhibits will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ Layne C. Hilton  
Layne C. Hilton